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EXAMINER

GRUN, JAMES LESLIE

ART UNIT

PAPER NUMBER

1641

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/673,558

Applicant(s)

MARQUARDT et al.

Examiner

James L. Grun, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some\* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
- ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7 20) ☐ Other:

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To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

The disclosure is objected to because of the following informalities: page 2, line 24, "PCT/WO97/43438" should be --WO 97/43438--. Appropriate correction is required.

5 The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10 Claims 1-21 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15 In claims 1-11, "the activity or concentration" and "the quantity of...label" lack antecedent basis. These claims are not clear because the preamble recites measuring the activity or concentration of a biomolecule but the body of the claims do not recite a step relating measuring label to measuring the activity or concentration of a biomolecule.

In claim 2, "pin-like" or "cone-like" are vague as to what shapes are contemplated by applicant because it is not clear how "like" a shape need be to a pin or cone to be encompassed by the invention for which coverage is desired.

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In claims 12-21, "the activity or concentration" and "the quantity of...label" lack antecedent basis. These claims are not clear because the preamble recites measuring the activity or concentration of a biomolecule but the body of the claims do not recite a step relating measuring label to measuring the activity or concentration of a biomolecule.

5 In claim 13, "pin-like" or "cone-like" are vague as to what shapes are contemplated by applicant because it is not clear how "like" a shape need be to a pin or cone to be encompassed by the invention for which coverage is desired.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

10 A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Eibl et al (U.S. Pat. No. 4,276,259).

15 Eibl et al disclose elongated elements, such as "platelets" or pins, which are secured to a holding band in a carrier and which are insertable into the recesses (i.e. wells) of a microtiter plate containing samples to be assayed (e.g. col. 3). Various competitive assay formats are taught using antigen or antibody bound to the elements and labelled antigen or antibody added to the sample (e.g. cols. 2, 4-9). The use of the carrier and methods for determination of antigens or antibodies,

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generally, is taught, including for factor VIII protein (e.g. col. 3) which is a notoriously well known enzyme cofactor (i.e. having an enzymatic activity). The reference teaches the carrier for the avoidance of complicated separating and washing procedures as used for prior assays performed with coated vessels, such as tubes.

5           Claims 12, 14-18, and 20-21 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Behnke et al (U.S. Pat. No. 5,573,921).

Behnke et al teach a dipstick immunodisplacement device and method wherein analyte in a sample displaces bound label from a specific binder bound to a solid phase which is dipped into the vessel containing the sample (e.g. col. 9 and Figs. 1A-1C).

10           The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

15           (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20           (c) Subject matter developed by another person, which qualifies as prior art only under one or more subsections (e), (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

25           This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

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Claims 1-21 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of Marquardt et al (WO 97/43438), Eibl et al (U.S. Pat. No. 4,276,259), Fish et al (U.S. Pat. No. 5,126,276), and Köhler (U.S. Pat. No. 4,822,565).

5 Marquardt et al teach solid phase assays, both competitive and non-competitive, for bioactive substances, including enzymes and their inhibitors, essentially as instantly disclosed except for being performed in microtiter plates rather than on an insertable solid phase.

The teachings of Eibl et al are as set forth previously and differ from the invention as instantly claimed in not specifically teaching determination of enzymes and in not teaching label bound to the elongated elements.

10 Fish et al teach the general use of coated comb-like carriers for assays to detect binding of a variety of receptor-analyte pairs, such as enzyme-substrate, antibody-antigen, antigen-antibody, receptor-toxin, receptor-drug, or complementary nucleic acid pairs (col. 6, lines 14-40).

15 Köhler teaches a comb-like carrier coated with antigens or antibodies for immunological assays as an alternative to coated microtiter plates, using a microtiter plate only as a vessel for multiple samples.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have substituted the comb-like carriers known to the art, as taught in Eibl et al, Fish et al, and Köhler, for the microtiter plates in the assays of Marquardt et al because Eibl et al, Fish et al, and Köhler teach these well known carriers generally for the performance of a variety of  
20 competitive and non-competitive solid-phase receptor-ligand assays, including specifically for

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enzyme-substrate interactions (Fish et al), as a substitute for coated vessels, such as the wells of a microtiter plate (Köhler) or individual tubes (Eibl et al), one of ordinary skill in the art would have had a reasonable expectation that the comb-like carriers known to the art as taught in Eibl et al, Fish et al, and Köhler would perform their desired function of phase separation in the assays of Marquardt  
5 et al, and one would have been motivated to use the carriers for their well known benefits as taught in the references of Eibl et al, Fish et al, or Köhler, such as for the avoidance of complicated separating and washing procedures (Eibl et al), or for ease of use, cost effectiveness, and reproducibility (Köhler).

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the  
10 absence of evidence to the contrary.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Ishikawa et al (U.S. Pat. No. 5,888,834) teach immune complex transfer immunoassays using both a well and dip stick solid phases.

15 Fisher Scientific teaches a beaded lid for simultaneous immunoassay of the wells of a microtiter plate.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (703) 308-3980. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

5 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (703) 305-3399.

The phone numbers for official facsimile transmitted communications to TC 1600, Group 1640, are (703) 872-9306, or (703) 305-3014, or (703) 308-4242. Official After Final communications, only, can be facsimile transmitted to (703) 872-9307.

10 Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. The above inquiries, or requests to supply missing elements from Office communications, can also be directed to the TC 1600 Customer Service Office at phone numbers (703) 308-0197 or (703) 308-0198.

  
James L. Grun, Ph.D.  
February 15, 2002



CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800 1641